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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,019	02/07/2001	Mark William Doane	0100/0090	6226

21395 7590 12/31/2003
LOUIS WOO
LAW OFFICE OF LOUIS WOO
717 NORTH FAYETTE STREET
ALEXANDRIA, VA 22314

EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/31/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,019

Applicant(s)

DOANE ET AL.

Examiner

Teena K Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,7,10,11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). (Note lined through address of inventor Jim Thomas).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brain (5,305,743).

Brain in a mask discloses a soft cuff member (13), said cuff member having a substantially hollow annular shape (Figs. 1, 2, 2A); and a rigid mount member (12), said mount member being more rigid than said cuff member (13) and being of generally funnel shape (Fig. 1), and wherein said cuff member is inflatable and is moulded with said mount member (Col. 2, lines 67, 68 and Col. 3, lines 1-34).

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With respect to claim 3, Brain discloses wherein said cuff member (13) and mount member (12) are moulded integrally as a single piece (Col. 2, lines 67, 68 and Col. 3, lines 1-34).

With respect to claim 6, Brain discloses wherein said mask is a laryngeal mask (Abstract) and said cuff member is adapted to seal with tissue in the region of the hypopharynx (Col. 9, lines 48-58) and it is inherent and well-known in the art that a laryngeal mask cuff is adapted to seal with tissue in the region of the hypopharynx which provides the needed seal.

With respect to claim 10, Brain discloses a tube (11) and a mask (Fig. 1) attached with one end of the tube, wherein said mask comprises: a mount member (12) generally funnel shape attached with said tube (11); a cuff member (13), said cuff member being of substantially annular shape and being softer than said mount member, wherein said cuff member is inflatable (via 17) and is moulded integrally with said mount member as a single piece (Col. 2, lines 67, 68 and Col. 3, lines 1-34).

With respect to the limitation of "...by rotational moulding..." the limitation of the claims are directed to a process of how the mount member and cuff are formed and therefore, patentable weight is only given to the product by process and not the process itself. In the instant application, the product being the mask. Therefore the examiner maintains the art rejection of claims 1 and 10 in view of Brain, because Brain reads on the claimed limitations since patentable weight is only given to the mask not the process of making by rotational moulding. "Even though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,305,734).

The difference between Brain and claim 4 is the mount member pre-formed and the cuff member molded with said mount member. Brain discloses a cuff member (13) and a mount member (12). Brain does not disclose the mount member pre-formed and the cuff member molded to the mount member. Applicant has not disclosed that having the mount member pre-formed and the cuff member molded to the mount member solves any stated problem or is for any particular purpose. Moreover, it appears that

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whether the mount member is pre-formed and molded to the cuff member the mask would perform equally well to seal the hypopharynx. Accordingly, having the mount member preformed and the cuff member molded to the mount member is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Brain.

With respect to claims 11 and 13 note rejection of claims 1 and 4 above, also see comments on the product-by-process noted above with respects to claims 1 and 10.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,305,743) in view of Sullivan et.al. (5,243,971).

The difference between Brain and claim 7 is wherein said mask is a facemask.

Sullivan teaches a face mask (19) having a soft cuff member (13) and a mount member (24) molded with said mount member (Col. 2, lines 50-67) providing a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user (Col. 2, lines 45-49 and Col. 4, lines 12-23).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the laryngeal mask of Brain to employ any well-known face mask doing so would have provided a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user including the face mask taught by Sullivan.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 10, and 11 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

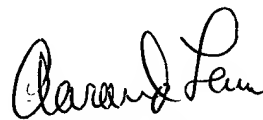
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Teena K Mitchell
Examiner
Art Unit 3743
December 30, 2003



Aaron J. Lewis
Primary Examiner